IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

REPLY IN SUPPORT OF PLAINTIFFS' AMENDED MOTION FOR PRELIMINARY INJUNCTION

The Intervenors incorrectly believe that *Dobbs v. Jackson Women's Health Organization* gave state legislatures a free pass to restrict abortion, insulated from judicial review. *Dobbs* did no such thing. The U.S. Constitution requires that in regulating abortion—as in regulating other medical care—states must still act rationally. Although rational basis is a deferential standard, it is not "toothless." *See, e.g., Matthews v. Lucas*, 427 U.S. 495, 510 (1976). Because the Hospitalization and IUP Documentation Requirements are not rationally related to patients' health, they are unconstitutional. The IUP Requirement is also unconstitutionally vague, as this Court has already held.

I. Courts Have Struck Down Numerous Laws Under the Rational Basis Test.

Intervenors are wrong that the rational basis test requires courts to accept at face value the government's claim that a rational relationship to a legitimate state interest exists. If that were true, no rational basis claim would succeed. To the contrary, courts have struck numerous laws under this test. For example, in *United States Department of Agriculture v. Moreno*, 413 U.S. 528 (1973), the Court struck down as irrational a prohibition on food stamps for households composed of unrelated individuals. The Court rejected the argument that the prohibition was rationally related to the goal of preventing fraud after looking at other laws protecting the food stamp program from abuse. *Id*. at 536-37. *See also Romer v. Evans*, 517 U.S. 620, 632 (1996) (holding that, even under rational basis, "we insist on knowing the relation between the classification adopted and the object to be obtained"); *Hooper v. Bernalillo Cnty. Assessor*, 472 U.S. 612, 619-23 (1985); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 446 (1985); *Zobel v. Williams*, 457 U.S. 55, 61-66 (1892); *Weinberger v. Wiesenfeld*, 420 U.S. 636, 648 (1975); *Catherine H. Barber Mem'l Shelter, Inc. v. Town of N. Wilkesboro Bd. of Adjustment of Town of N. Wilkesboro*, 576 F. Supp. 3d 318, 343 (W.D.N.C. 2021).

Furthermore, any presumption of rationality can be overcome by "common knowledge" or evidence. *Borden's Farm Prods. Co. v. Baldwin*, 293 U.S. 194, 209 (1934); *see also St. Joseph Abbey v. Castille*, 712 F.3d 215, 226 (5th Cir. 2013) (holding that deference to the legislature does not demand that the judiciary ignore the history or context of the law); *Merrifield v. Lockyer*, 547 F.3d 978, 990 (9th Cir. 2008); *Craigmiles v. Giles*,

312 F.3d 220, 224 (6th Cir. 2002).[1] Thorough review is all the more important *because* abortion, which is politically stigmatized, is at issue. As *Moreno* holds, a "desire to harm a politically unpopular group cannot constitute a legitimate governmental interest." 413 U.S. at 534. *See also Romer*, 517 U.S. at 633 (holding that "classifications . . . drawn for the purpose of disadvantaging the group burdened by the law" are irrational); *City of Cleburne*, 473 U.S. at 448.

II. The Hospitalization Requirement Is Unconstitutional

A. The Hospitalization Requirement is not rationally related to abortion safety.

Intervenors attempt to characterize abortion as unsafe to justify *any* abortion restriction as reasonably related to health and safety. Int. Br. at 2. But as discussed, *supra* Part I, *Dobbs* did not give states free rein to regulate abortion without any legitimate safety rationale. Even under rational basis, courts do not "rubber stamp the classification no matter the facts" simply because the government invokes "magic words" like "safety"; rather, the government must "establish that its safety concerns are based on an actual material distinction." *Mem'l Shelter*, 576 F. Supp. 3d at 341.

Intervenors' characterization of abortion safety is flatly wrong: as recognized by expert bodies like the National Academies of Sciences, Engineering, and Medicine and the

[1] Intervenors rely on *Gonzales v. Carhart*, 550 U.S. 124 (2007), to claim that the General Assembly had wide discretion because of the "medical uncertainty" of abortion's safety. Def.-Intervenors' Resp. in Opp'n to Pls.' Am. Mot. for Prelim. Inj. ("Int. Br.") at 10, 29, DE 65. But no such uncertainty exists, as discussed below. Moreover, *Gonzales* held that courts retain an independent duty to review factual findings. 550 U.S. at 165.

American College of Obstetricians and Gynecologists (ACOG), abortion is overwhelmingly safe, including *specifically in outpatient clinics*, where the vast majority of abortions happen. *See* Decl. of Katherine Farris, M.D. ("First Farris Decl."), DE 49-1 ¶¶ 29-38; Rebuttal Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. ("Boraas Rebuttal Decl.") ¶¶ 6-14, 31, attached as Exhibit 1. Indeed, the Attorney General admits abortion is safe, Def. Att'y General Stein's Answer, DE 64 ¶ 76, and the Department of Health and Human Services agrees that "the risk of serious complications related to abortion is low" and the maternal mortality rate is higher for childbirth than abortion, Answer of Kody H. Kinsley, DE 55 ¶¶ 53, 70. Dr. Wubbenhorst's suggestion that abortion safety data is "incomplete," *see* Int. Br. at 2, 10 (citing Decl. of Monique Chireau Wubbenhorst, M.D., M.P.H. ("Wubbenhorst Decl."), DE 65-1 ¶¶ 64, 96, 98, 101), ignores the medical consensus and misunderstands abortion safety data. Boraas Rebuttal Decl. ¶¶ 8-14, 21-24.[2]

The observation that hospitals have more resources than clinics does not help Intervenors. *See* Int. Br. at 9, 12. The operative question is whether these differences matter *for purposes of providing abortion safely after twelve weeks of pregnancy*. *Mem'l Shelter*, 576 F. Supp. 3d at 338. As previously detailed, complications from abortion are extremely rare; complications that arise during the procedure are usually treated on-site; and in the

[2] *See also EMW Women's Surgical Ctr. v. Cameron*, No. 22-CI-3225, at 4 (Cir. Ct. Jefferson Cty., Ky. July 22, 2022) (attached as Exhibit 3) (finding that in her testimony, Dr. Wubbenhorst had been "unable to provide any evidence to support her criticism" of the "accuracy of abortion statistics in general"), *rev'd on other grounds by Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 664 S.W.3d 633 (Ky. 2023).

exceedingly rare event of a complication requiring hospitalization, patients are safely transferred. Memo. of Law in Supp. of Pls.' Am. Mot. for Prelim. Inj. ("Am. PI Memo"), DE 49, at 6; Rebuttal Decl. of Katherine Farris, M.D. ("Farris Rebuttal Decl."), ¶¶ 5-8, attached as Exhibit 2; Boraas Rebuttal Decl. ¶¶ 8, 11, 16, 33-36. Moreover, any characteristics distinguishing hospitals from clinics are relevant only for the very few patients who are sick enough to need those resources and whom PPSAT would not treat. Boraas Rebuttal Decl. ¶ 34.

Contrary to Intervenors' claim, Int. Br. at 4–5, 9, it is not rational to require *all abortion patients* to be hospitalized simply because a very small number may experience a complication requiring hospitalization. Farris Rebuttal Decl. ¶ 8; Boraas Rebuttal Decl. ¶¶ 30-34; *see, e.g.*, *O'Day v. George Arakelian Farms, Inc.*, 536 F.2d 856, 860 (9th Cir. 1976) (finding a law irrational where it was "grossly excessive" in relation to government interest). Indeed, the General Assembly has not required that people go to hospitals for vasectomies or colonoscopies, or to have wisdom teeth removed. Taken to its logical conclusion, Intervenors' argument would allow the legislature to force all medical procedures, no matter how minor, into hospital operating rooms because no procedure is completely risk-free.[3]

[3] Intervenors' "articulat[ion]" of Plaintiffs' argument is a straw man: undoubtedly "the Constitution does not *prohibit* second-trimester surgical abortions to be performed in a hospital." Int. Br. at 10 (emphasis added). What the Constitution prohibits is *requiring* hospitalization for second-trimester abortions, where procedures of equal or greater risk are not subject to that requirement.

Boiled down, Intervenors' only justification for the Hospitalization Requirement is that "[a]bortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." Int. Br. at 15. But Intervenors do not raise potential life as a state interest for good reason: wherever abortions are performed, they end pregnancy, so the Hospitalization Requirement is not rationally related to any interest in potential life. And in *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 167–69, 173 (4th Cir. 2000), the Fourth Circuit upheld under rational basis review an abortion regulation because it "largely track[ed]" the "standards and guidelines issued by the ACOG, Planned Parenthood, and the National Abortion Federation" and thus was reasonably directed at promoting health—not because "'distinguishing between abortion services and other medical services'" is rational *per se*, as Intervenors argue. *See* Int. Br. at 15 (quoting *Bryant*, 222 F.3d at 173). The Hospitalization Requirement is irrational for the same reason the *Greenville* regulations were not: it runs counter to all reliable medical evidence and standards.

B. The Hospitalization Requirement draws arbitrary classifications based on stigma.

The Hospitalization Requirement restricts the availability of abortion but not procedures of equal or greater complexity or risk, thereby creating a classification based solely on abortion stigma in violation of the Equal Protection Clause. *See City of Cleburne*, 473 U.S. at 448 (striking down as irrational the city's requirement of a special use permit for a group home for people with mental disabilities while not requiring such a permit for

other similar uses). And where, as here, arbitrary distinctions give rise to both due process and equal protection claims, the two claims are often evaluated together. *See, e.g.*, *St. Joseph Abbey*, 712 F.3d 215; *Craigmiles*, 312 F.3d 220; Am. PI Memo at n.7.

Intervenors argue that the Hospitalization Requirement does not create classes of patients or physicians, but rather classes based on gestational age. Int. Br. at 14. This ignores that while Part II of the Act creates a hospitalization requirement for abortion, N.C. Gen. Stat. § 90-21.82A(c), Part IV provides for "planned birth outside of a hospital setting." N.C. Gen. Stat. § 90-178.4 (as amended by S.B. 20, § 4.3(d), effective Oct. 1, 2023). Rational basis analysis looks at a challenged statute's operation alongside other laws, not just the face of the statute itself. *See, e.g.*, *Moreno*, 413 U.S. at 536-37; *City of Cleburne*, 473 U.S. at 448. By requiring hospitalization for abortion but not procedures of greater risks, like childbirth, and procedures of equal or greater risk, including miscarriage management using identical techniques, Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. ("First Boraas Decl."), DE 49-2 ¶¶ 21, 24, 40; First Farris Decl. ¶ 40, the Hospitalization Requirement imposes stricter requirements on abortion based solely on political stigma. Farris Rebuttal Decl. ¶ 15. Thus, Plaintiffs need not show that the General Assembly was motivated by a "bare desire to harm" patients seeking abortion. Int. Br. at 16. Rather, the absence of a rational relationship to a legitimate state interest demonstrates as much.[4]

[4] Moreover, the General Assembly's line-drawing at twelve weeks is arbitrary and not rationally related to patient safety, because abortion patients receive the same

III. Plaintiffs Are Likely to Succeed on Their Claim that the IUP Documentation Requirement Is Unconstitutional.

A. The IUP Documentation Requirement is unconstitutionally vague.

Intervenors admit that the IUP Documentation Requirement carries criminal penalties, and therefore the standard for Plaintiffs' vagueness challenge is higher.[5] Int. Br. at 18. As this Court held at the TRO stage, Plaintiffs are likely to succeed on that challenge because the Act (1) "broadly allows abortions during the first twelve weeks of pregnancy" while (2) requiring documentation of an intrauterine pregnancy before providing medication abortion, which may be impossible at the earliest stages. TRO, DE 31 at 6-7. Moreover, the Attorney General agrees that the law is vague, Def. Att'y General Joshua H. Stein's Memo. of Law, DE 63 at 14-17, reinforcing Plaintiffs' argument that the statute is subject to arbitrary and discriminatory enforcement. Am. PI Memo at 16-18.

Intervenors attempt to cure the provision's vagueness in two unpersuasive ways. First, they claim that the scienter requirements of other statutory provisions should mollify Plaintiffs' concerns, Int. Br. at 18 (citing N.C. Gen. Stat. §§ 14-23.2(a)(1), 14-44, 14-45), but fail to explain how the scienter requirements for the fetal homicide and unlawful abortion statutes resolve the conflict between the two provisions discussed above. Second,

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aspiration procedure at eleven and thirteen weeks of pregnancy. First Farris Decl. ¶ 21; First Am. Compl., DE 42 ¶ 66; Boraas Rebuttal Decl. ¶ 32.

[5] Intervenors here too rely on *Greenville Women's Clinic*, but the challenged law in that case carried, at most, modest civil penalties, 222 F.3d at 161.

Intervenors combine the two provisions at issue and insert the word "only" to argue that the medication abortion is permitted "only" after the existence of an intrauterine pregnancy is documented. Int. Br. at 19. But this is an attempt to rewrite the statue, and it should be rejected. *See, e.g.*, *Legend Night Club v. Miller*, 637 F.3d 291, 302 (4th Cir. 2011). This Court should hold, as it did in its TRO, that Plaintiffs are likely to succeed on the merits of their vagueness claim.

B. Medication abortion is safe, and the IUP Documentation Requirement does not make patients with ectopic pregnancies safer.

Intervenors misunderstand and mischaracterize the scientific data on medication abortion's safety. For instance, Intervenors cite the FDA's Mifeprex label for the statement that "between 2.9% and 4.6% of women end up in the emergency room due to complications from chemical abortion," Int. Br. at 3, but ignore that the label also says the rate of hospitalization is 0.04-0.6%. Int. Br. Ex. 2, 8 tbl.2. More importantly, the FDA repeatedly has made clear that medication abortion is extremely safe. *See, e.g.*, FDA, *Ctr. for Drug Evaluation & Rsch., Med. Rev., Application No. 020687Orig1s020*, 47 (2016) (serious adverse events among mifepristone patients are "exceedingly rare, generally far below 0.1% for any individual adverse event").[6]

[6] Available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf. *See also Analysis of Medication Abortion Risk and the FDA report, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"*, Advancing New Standards in Reprod. Health (2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf; Boraas Rebuttal Decl. ¶ 11.

Intervenors also accuse Plaintiffs of providing "unapproved and dangerous drugs," Int. Br. at 22, by providing medication abortion through 11 weeks of pregnancy, *id.* at 3, despite mifepristone's proven safety at that gestational age. *See* First Farris Decl. ¶ 18; Boraas Rebuttal Decl. ¶ 52. This is a particularly startling assertion since the General Assembly amended the Act to *allow* the provision of medication abortion through twelve weeks. *See* Session Law 2023-65, DE 26-1 § 14.1(f); *see also* First Farris Decl. ¶ 18; Boraas Rebuttal Decl. ¶ 52.

Further, while Intervenors point out that risks associated with abortion increase as pregnancy continues, *see, e.g.,* Int. Br. at 3, they nevertheless defend the rationality of delaying medication abortion until "about five or six weeks LMP." *Id.* at 22. Prohibiting early abortion when it is safest is the model of irrationality.

Intervenors assert that "[c]hemical abortion is contraindicated for women with ectopic pregnancies." *Id.* at 3, 21. But medication abortion is contraindicated for ectopic pregnancies *because it does not treat them*, not because it increases the likelihood of negative outcomes. Farris Rebuttal Decl. ¶ 11; Boraas Rebuttal Decl. ¶ 50. The point of screening patients for ectopic pregnancy is not to prevent the nonexistent "danger[]," Int. Br. at 22, of providing medication abortion to a patient with an ectopic pregnancy. Rather, screening ensures these patients are promptly diagnosed and treated. PPSAT's evidence-based protocol does exactly that.

Contrary to Intervenors' claim, Int. Br. at 22, PPSAT does not "merely ask[] questions about the patient's medical history and current symptoms" to screen for ectopic

pregnancy.[7] Instead, PPSAT performs an ultrasound *and*, if a pregnancy is not visible, conducts further screening for ectopic pregnancy. First Farris Decl. ¶ 52; Farris Rebuttal Decl. ¶ 12. Patients with confirmed or suspected ectopic pregnancies are referred elsewhere for treatment. *Id.*; First Am. Compl. ¶ 54. But if the patient is determined to be at low risk of ectopic pregnancy and decides to proceed with a medication abortion, PPSAT simultaneously provides the medication abortion *and* conducts further testing to rule out ectopic pregnancy, drawing serial blood samples to test the levels of the pregnancy hormone hCG. First Farris Decl. ¶¶ 53–57; *see also* Farris Rebuttal Decl. ¶ 12.

Contradicting their own expert, Intervenors claim that the "only way" to diagnose ectopic pregnancy is by ultrasound, Int. Br. at 22. But as Dr. Wubbenhorst admits, an ectopic pregnancy can be ruled out "based on ultrasound *and quantitative (blood, hCG) pregnancy testing*." Wubbenhorst Decl. ¶ 254 (emphasis added). PPSAT does precisely this. Because medication abortion does not increase the risks associated with an ectopic pregnancy, Boraas Rebuttal Decl. ¶ 50, there is no downside to PPSAT's evidence-based practice of simultaneously providing medication abortion to low-ectopic-risk patients. First Farris Decl. ¶¶ 54. In fact, at least one study showed this protocol leads to earlier detection

[7] Intervenors misrepresent even this component of the screening process. They incorrectly assume that a patient who reports no symptoms will be inaccurately categorized as at low risk of ectopic pregnancy. This ignores the additional steps in PPSAT's protocol and overlooks the fact that patients who report ectopic pregnancy risk factors would not be deemed low-risk, even if asymptomatic. *See* First Farris Decl. ¶ 52; First Boraas Decl. ¶ 49.

of ectopic pregnancy.[8]

Intervenors also claim that a hypothetical patient with an ectopic pregnancy could receive a medication abortion and then not receive treatment for the ectopic pregnancy. But as Intervenors admit, "[t]he IUP documentation requirement neither commands nor prevents a physician from referring a patient for ectopic evaluation." Int. Br. at 24. While PPSAT cannot force patients to return for follow-up based on hCG test results, its protocol ensures those test results (and their potential significance) will be communicated to patients, whereas the IUP Documentation Requirement both denies early medication abortion care *and* does nothing to provide a mechanism for "ensur[ing] the patient is not suffering from an ectopic pregnancy." *Id.* at 24; Farris Rebuttal Decl. ¶ 11. Additionally, Intervenors' suggestion that patients will confuse the symptoms of an ectopic rupture with those of a medication abortion, Int. Br. at 23, is extremely unlikely given PPSAT's thorough counseling and the differences between the severe, sharp pain associated with ectopic rupture versus the midline cramping that medication abortion patients often experience. Boraas Rebuttal Decl. ¶ 53.

Finally, although Intervenors claim that the IUP Documentation Requirement "would prevent serious health consequences to women with undiagnosed ectopic pregnancies," Int. Br. at 22, they callously argue that whether PPSAT's protocol leads to

[8] Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics & Gynecology 771 (2022).

earlier or more accurate diagnosis of ectopic pregnancy "has no bearing on the law" and its rationality. *Id.* at 24. Intervenors' disregard for the health and safety benefits of PPSAT's evidence-based protocol underscores its irrationality. *See Merrifield*, 547 F.3d at 992.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' amended motion for a preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Relying on the word count function of Microsoft Word, I hereby certify that this brief is 3,115 words in length and, therefore, complies with the word limitation of 3,125 words for briefs prescribed by Local Rule 7.3(d)(1).

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CERTIFICATE OF SERVICE

I hereby certify that, on August 18, 2023, I electronically filed the foregoing with the clerk of the court by using the CM/ECF system, which served notice of this electronic filing to all counsel of record.

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